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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/714,987	09/17/1996	HUGH SHARKEY	17616-705	4099
23715	7590	03/11/2005	EXAMINER	
JOEL R. PETROW SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116			SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 03/11/2005

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 08/714,987
Filing Date: September 17, 1996
Appellant(s): SHARKEY ET AL.

Phyllis K. Kristal
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 13, 2004.

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This is in response to the brief on appeal filed August 13, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The amendment after final rejection filed on November 17, 2003 has not been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The rejection of claims 89-94 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because appellants arguments regarding the patentability of claims 77, 80, 81, 85, 87, and 88 are limited to the assertion that neither Cosman et al (1984) nor any of the references with which it has been combined do not provide the claimed sensor placement.

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references with which it has been combined do not provide the claimed sensor placement.

However, this is also the crux of the argument put forth regarding claims 48, 50, 53, 74, 75, 78, 79, 82, 83 and 86.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

NUMBER (TITLE)	NAME	DATE
4,966,597	Cosman	October 30, 1990
WO 92/15664	Makower et al	August 19, 1993
Theoretical Aspect of Radio frequency Lessons in The Dorsal Root Entry Zone	Cosman et al	1984

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 48, 50, 53, 74, 75, 77-83, and 85-88 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cosman et al (1984).

Wherein the interior of the electrode is the conductive material and the surface of the electrode is the surface material. Any interstitial fluid present will provide the composite

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temperature readings referred to. See Figure 2 and 3 and page 946, column 2 to page 948, column 2.

Claims 74, 76, 82, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman et al (1984) in combination with Cosman ('597). Cosman et al (1984) provide the teaching set forth above. Cosman ('597) teach forming electrodes of stainless steel. It would have been obvious to the artisan of ordinary skill to form the electrode of Cosman et al (1984) of stainless steel since this is a well known electrode material, and useful for forming thermocouple junctions, thus producing a device such as claimed.

Claims 54, 55, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman et al (1984) in combination with Makower et al. Cosman et al (1984) provide the teachings set forth above. Makower et al teach the equivalence of microwave, radio frequency, and resistive heating in energy delivery devices. It would have been obvious to the artisan of ordinary skill to employ a resistive or microwave tissue heater in the device of Cosman et al (1984), since these are well known equivalents in the art, as taught by Makower et al and provide no unexpected results, thus producing a device such as claimed.

Claims 89-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Cosman et al (1984). Makower et al teach a method such as claimed except for the specific recitation of moving and returning the applicator and the sensor completely enclosed by the thermally conductive material of the probe. Cosman et al (1984) teach a thermistor surrounded by conductive material. It would have been obvious to the artisan of ordinary skill to employ the energy applicator of Cosman et al (1984) in the method of Makower et al, since Makower et al teach no particular form for the high frequency applicators,

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and to remove the applicator and perform a multiple step therapy and for example as taught by Makower et al page 20, and re-insert the applicator e.g. if subsequent diagnosis determined that further treatment is needed, thus producing a method such as claimed.

(11) *Response to Argument*

Issues

The core issue is the location of the thermal sensor of Cosman et al (1984). Appellants' contention appears to be that Cosman et al (1984) teaches "that the sensor is built into the small sharpened tip of the device, and that in use the tip is located in the spiral cord." And that since the entire tip is located in the tissue that "Cosman's sensor is positioned only to detect thermal energy from the selected site, not from the adjacent fluid medium "(see Brief on Appeal, page 4, second full paragraph of larger type).

The examiner must respectfully disagree. Appellants' Brief, in the paragraph immediately preceding that quote above, discuss Figure 3 and the second full paragraph on page 11 of Appellants' disclosure with regard to this issue. Turning first to figure 3, the examiner firstly notes that if the device of Cosman et al (1984) were placed in the environment and the manner shown therein, it would function just as Appellants' device. Proceeding to the noted passage on page 11, the fluid medium is described as follows: "Fluid medium (gas, liquid, or combination) 30 maybe flowing as would result from irrigating the collagen containing tissue 28 or it may be substantially less dynamic or non-moving. Further fluid medium 30 need only be partially fluid and contain bone, portions of organs or other bodies and the like." This very broad definition clearly reads upon even the interstitial fluid (such as the cellar contents and blood that would be released by the cells ruptured on insertion of the probe) that appellants refer

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to in the first full paragraph of larger type on page 11 of the Brief on Appeal, as well as the “extrastitial fluid” also referred to therein such as the cerebrospinal fluid (CSF) which surrounds the tissue upon which Cosman et al discuss operating.

Appellants then note that to establish inherency that the evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference,” citing ATD Corp v. Lydall, Inc. The examiner respectfully notes that the presence of liquid at the site is clearly shown by Cosman et al in the paragraph bridging columns 1 and 2 of page 947 thereof which states “before temperatures monitoring the boiling point was after exceed, resulting in a “popping” lesion. In this situation the current meter would fall rapidly, the voltage meter would rise, and gas and steam formed at the tip would be forced up the shaft of the electrode” (emphasis added) clearly reaching of the boiling point and production of steam at the tip required the presence of liquid at that tip.

Regarding claims 77, 80, 81, 85, 87, and 88, appellants argue that “Cosman et al (1984) is silent as to the relative position of the sensor and any conductive material other than specifying that the sensor is built into the small sharpened tip of the device” (see Brief on Appeal, page 5, last sentence). However, beginning at page 946, column 2, line 5 to line 3 in column 1 on page 447, Cosman et al (1984) states “the two most important parameters determining the temperature distributions are the temperature next to the electrode’s surface and the radius of the electrode... r f heat is generated in the tissue, not in the electrode tip and, because the tip lies in the tissue, it absorbs heat from it. For a proper electrode design, the electrode will not absorb much heat from the tissue, thus at equilibrium the tip temperature nearly equals that if the hottest tissue adjacent to it.” Clearly for the temperature registered by the thermocouple accurately reflect the tissue

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temperature, the material between the tissue and the temperature sensor (i.e. electrode material) must be thermally conductive. As set forth above.

Claims 74, 76, 82, and 84

Appellants sole argument here is that “Cosman ‘597 does not overcome the differences of Cosman et al (1984).” As set forth above Cosman et al (1984) is not deficient for meeting the claims to which it is applied, thus this argument is not convincing.

Claims 54, 55, and 74

Appellants sold argument here is that “Makower et al does not overcome the deficiencies in Cosman et al (1984).” As set forth above Cosman et al (1984) is not deficient for meeting the claims to which it is applied.

Claims 89-94

Regarding claim 89, as Cosman et al (1984) is not deficient, as set forth above, Appellants unsupported assertion to the contrary is not convincing.

Regarding claim 90, the examiner apologizes for the erroneously reproduced language of the previous Final Rejection which notes that page 20 in Makower discloses removing the applicator (see page 20, first sentence) and that re-insertion thereof after a diagnosis step showing further treatment being required would have been obvious to the artisan of ordinary skill. The examiner notes that the rejection based on the obviousness of the re-insertion for treatment purposes has been of record continuously since October of 2002, when it was raised in the First Action on the Merits mailed at that time and was not disputed in either the response to the action nor in the response to the subsequent Final Action, which also raised the issue. As such Appellants challenge of the point is unreasonable. This said, however, the examiner asserts

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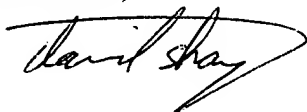
that it is not merely obvious, but a surgeons duty to re-treat a site that is shown to require further treatment and Appellant has produced no showing to the contrary in the two years during which Appellant has been aware of this finding by the examiner.

Regarding claim 93 applicant argues that neither Cosman et al (1984) nor Makower et al suggest sensing the component temperature "as discussed above." The examiner notes that this issue has already been argued above and reference is made to the preceding arguments in this regard. Applicant also argues that neither Makower et al nor Cosman et al teach "delivering an adjusted level of energy comprises delivering a lower level of energy to reduce stray contractions in the [adjacent] fluid medium." The examiner notes that Cosman et al teach that prior art lesions were produced using controlled power and current (see page 945, column 2, the fifth sentence of the first full paragraph) and subsequently notes that prior to using temperature control" the boiling point was after exceed." Thus using unvaried power caused boiling, but after employing temperature control, this problem was alleviated, thus clearly the temperature control results in reduced power, and avoided boiling. Since power is merely the time rate of energy used, if the power is reduced the level of energy is also reduced.

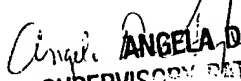
Conclusion

It is the examiner's firm opinion that the appealed claims are not patentable for the reason argued above. Appellant has presented no convincing argument as to why the rejections set forth above are not obvious or proper. Therefore, it is respectfully submitted that the Final Rejection be affirmed. For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,



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